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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/696,360      | 10/29/2003  | Martin Frank         | ROCHE-P0019         | 6700             |

63049 7590 02/07/2008  
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| EXAMINER |
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LEVKOVICH, NATALIA A

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1797

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| MAIL DATE | DELIVERY MODE |
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02/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                              |  |
|------------------------------|-------------------------------|------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/696,360 | Applicant(s)<br>FRANK ET AL. |  |
|                              | Examiner<br>Natalia Levkovich | Art Unit<br>1797             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 14-16 and 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13, 17, 18 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09/02/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election of claims 11-13, 17-18 and 38-43 made without traverse in the reply filed 11/06/2007 is acknowledged.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the test element analysis system having both a test element holder and a gripping device; the frame with the diameter increasing from the gripping rim in both 'spatial directions running vertical to the test field plane', as recited in claims 11, 43, as well as the gripping device comprising a part of the evaluation instrument, as recited in claim 12, must be clearly shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate

figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 11 recites a test element analysis system having both a test element holder and a gripping device. Examiner found no support for this limitation in the specification.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13, 17-18 and 38-43 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites 'the analytical investigation of liquid samples, in particular of body liquids of humans or of animals'. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claim recites the broad recitation of 'liquid samples', and the claim also recites the 'body liquids of humans or of animals' which is the narrower statement of the range/limitation.

With respect to the limitation of line 12, 'with a measuring device for measuring

the change', it is not clear whether the limitation pertains to the evaluation instrument ('with a test element holder... and with a measuring device') or to the test field being 'brought into contact with the sample and with a measuring device'. For clarity, the latter is assumed.

In lines 15-17, the 'outer circumference of the test elements' and the 'diameter of the frame', lack antecedent basis. Do the intended test elements and frames have a circular shape? See also claim 38.

In lines 18-19, the frame increasing from the gripping rim in 'spatial directions running vertical to the test field plane', is unclear, because the claim does not set forth the orientation in space neither for the test element, nor for the test field. Additionally, the claim does not set forth important structural inter-relationships between the gripping device and the elements of the evaluation instrument.

In claim 18, the front end of the gripping section', lacks antecedent basis.

With respect to claim 40, 'a little higher', is a relative term.

In claim 41, the terms 'internal cross section' and 'outer cross section', are unclear.

In claim 42, the 'direction of the test field plane', is unclear.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 11-13, 17 and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerr et al. (US 5075079) in view of Kidal et al. (US 5507388) and further in view of Cole et al. (US 7205159).

Kerr discloses a test slide analysis system including, as best shown in Figures 16-17, slide transfer means 18 ['gripping device', 'holder' of an evaluation instrument] having jaws ['gripping arms'], slide compartment 26 ['test element storage container' / 'magazine'] with withdrawal slot 44, the compartment being configured for accommodating a stack of slides 28 ['test elements'], each slide comprising a circular area 29 ['test field'] surrounded by a rectangular area ['frame', not indexed]. Figure 18 shows the transfer device taking a test slide by opposite side walls forming a 'gripping rim', the slide being 'in sealing contact with the inner wall' 24 of the storage compartment 26.

Kerr does not specify the shape of the side rims of the test elements. Kidal et al. discloses in Figure 6 test elements with side walls profiled such that

the distance between the center of the element and the side would decrease in both vertical directions from gripping lip ['gripping rim'] 132 formed by slanted portions 130 of the side wall. It would have been within the ordinary skill of an artisan at the time the invention was made to have profiled the sides of the test elements in the modified apparatus of Kerr in a similar manner, in order to provide better engagement between the gripping device and test elements. In the alternative (depending on a configuration of the of the gripping arm surface), it would have been also within the ordinary skills, to have profiled the sides of the test elements such that the distance between the center of the element and the side wall would increase in both vertical directions from the gripping rim, which would also provide a better engagement between the gripping device and the test element.

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kerr et al. in view of Kidal et al., and further in view of Marbeuf (US 2608433). Kerr does not teach the distance between the gripping arms decreasing towards the 'front' of the gripping device. However, such feature is very well known (see, for example, Figure 2 of Marbeuf). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed gripping arms having portions shaped to enclose the slides in the modified apparatus of Kerr, in order to further improve engagement between the gripping device and the test element.




**Conclusion**

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jill Warden  
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